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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

This Clinical Trial Network was aimed at forming a collaborative linkage between the UAB Comprehensive Cancer Center, community-based oncology practices and pharmaceutical sponsors, and providing access to women with breast cancer within the community to high priority clinical trials. To-date three phase I/II clinical trials and three phase III clinical trials have been activated at the network sites in Georgia (GCS), and a total of 49 patients have been accrued in the past 12 months. In addition, we have recently activated our first network site in Birmingham, AL. Overall, the DOD funded Clinical Trial Network has the unique potential of providing access to women with breast cancer in the community to cutting-edge, novel therapeutic trials previously only available at academic centers. We have been able to demonstrate that the DOD funding mechanism has successfully contributed to the conduct of high quality clinical trials in the community setting by providing funding for the infrastructure and research personnel in conjunction with training, leadership and oversight provided by the academic center.

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Introduction

In 2000 we initiated a Clinical Trials Network linking the UAB Comprehensive Cancer Center with community oncology groups for the conduct of early breast cancer clinical trials using reagents developed by Cancer Center scientists, collaborators at the NCI and/or pharmaceutical partners. The Network currently encompasses 20 full service oncology practices in metropolitan Atlanta, and we have recently activated one site in Birmingham, Alabama. Clinical research coordination and leadership is provided by the UAB Cancer Center. The network activity is governed by a central IRB (UAB IRB) with centralized administrative oversight for budget and contracting (UAB Grants and Contracts Office), and oversight data management and data analysis provided centrally by the Cancer Center's Clinical Studies Unit (Biostatistics Shared Facility).

The specific aims are to:

1. Establish and operate an efficient clinical trials network linking the UAB Comprehensive Cancer Center with community oncologists for the specific purpose of promoting the conduct of innovative early clinical trials in the field of breast cancer.

2. Coordinate a collaborative relationship with pharmaceutical/bioindustry partners such that new treatment strategies using novel reagents can be designed and efficiently tested in patients with breast cancer.

3. Provide a web-based automated patient screening and enrollment system to promote efficient breast cancer patient accrual throughout the network.

4. Provide an efficient clinical trial management team and biostatistical analysis unit to ensure optimal data management, analysis and reporting.

2001-2002 Progress Report

This is the second annual report for the UAB Clinical Trial Network (UAB-CTN) established in collaboration between the UAB Comprehensive Cancer Center and community-based oncology practices in Alabama and Georgia. To date the affiliation between UAB and Georgia Cancer Specialists has been established and operational for the past two years. A total of six clinical trials involving breast cancer patients have been activated at the network sites in Georgia. In this past year, we have also activated one site in Birmingham, AL and one protocol has been activated at this site, however only non-breast cancer patients have been accrued to the protocol thus far. A major breakthrough in the ability to conduct breast cancer trials through this DOD funded mechanism was achieved in this past funding year when the DOD HSRB agreed to permit UAB IRB to provide central regulatory oversight and approval for the conduct of trials at the network sites. As a result we have been able to activate clinical trials much more efficiently, reduce duplication of IRB effort, and our accrual will demonstrate the resulting progress.

Six clinical trials have been activated within the network with a total accrual of 49 patients in the past 12 months.

The recent activation of Birmingham Hematology-Oncology, L.L.C. as a network site is a major accomplishment, demonstrating the ability of the UAB Comprehensive Cancer Center to work with community oncology practices in the city to form alliances in the area of clinical research for the benefit of patients. Furthermore, recent improvement in the infrastructure and administrative oversight as well as training of research staff at the Georgia Cancer Specialists sites have substantially improved the overall ability to conduct clinical trials at these sites. Given both these achievements, we anticipate further progress in terms of study activation and accrual in the next funding period.

Key Research Accomplishments

The UAB-Community Breast Cancer Clinical Trial Network includes three designated research clinics in Atlanta drawing patients from 20 GCS clinics, including one phase I/II site dedicated to the conduct of early clinical trials, and two sites involved in the conduct of phase II/III clinical trials. Most recently one network site has been activated at Birmingham Hematology-Oncology, L.L.C. in Birmingham, AL for the conduct of phase II/III clinical trials.

A total of six breast cancer protocols have been activated at the GCS sites and one protocol at Birmingham Hematology-Oncology, L.L.C. site.

The following table provides the accrual for each of the six protocols over the past 12 months compared to the previous 12 months.

UAB-Community Breast Cancer Clinical Trials Network

Protocol	**Patient Accrual – June 15, 2000-June 14, 2001**	**Patient Accrual – June 15, 2001-June 14, 2002**
UAB 9912 – A Phase II Study Using SGN-15 (cBR96-Doxorubicin Immuno-conjugate) in Combination with Taxotere for the Treatment of Metastatic or Recurrent Breast Carcinoma	2	2
UAB 0009 – A Phase I Clinical and Pharmacokinetic Evaluation of Oral CI-1033 Given as a Single Dose Daily in Patients with Advanced Nonhematologic Malignancies	Not active – 0	2

Protocol	Patient Accrual – June 15, 2000-June 14, 2001	Patient Accrual – June 15, 2001-June 14, 2002
UAB 0028 – A Multicenter, Open-Label, Phase III, Randomized, Active-Controlled Trial Evaluating the Efficacy, Safety, and Pharmacokinetics of rhuMAb VEGF (BEVACIZUMAB), in Combination with Capecitabine Chemotherapy, in Subjects with Previously Treated Metastatic Breast Cancer	Not active – 0	12
UAB 0047 – A Multicenter Phase III Randomized Trial Comparing Docetaxel in Combination with Doxorubicin and Cyclophosphamide (TAC) Versus Doxorubicin and Cyclophosphamide Followed by Docetaxel (AC → T) as Adjuvant Treatment of Operable Breast Cancer HER2NEU Negative Patients with Positive Axillary Lymph Nodes (BCIRG 005)	Not active – 0	24
UAB 0106 – A Multicenter Phase Ill Randomized Trial Comparing Doxorubicin and Cyclophosphamide Followed by Docetaxel (AC→T) With Doxorubicin and Cyclophosphamide Followed by Docetaxel and Trastuzumab (AC→TH) and With Docetaxel, Platinum Salt and Trastuzumab (TCH) in the Adjuvant Treatment of Node Positive and High Risk Node Negative Patients with Operable Breast Cancer Containing the Her2Neu Alteration	Not active – 0	5

Protocol	Patient Accrual – June 15, 2000-June 14, 2001	Patient Accrual – June 15, 2001-June 14, 2002
UAB 0152 – A Multicenter Phase 2 Study of CI-1040 in Patients with Advanced Non-Small Cell Lung Cancer, Breast Cancer, Colon Cancer, or Pancreatic Cancer	Not active – 0	4
Total Trials Activated	Total Accrual 2001	Total Accrual 2002
6	**2**	**49**

Three publications involving DOD funded trials conducted with the Network were presented at the recent ASCO 2002 meeting. One abstract has been submitted for the Era of Hope 2002 – Department of Defense Breast Cancer Research Program Meeting.

Reportable Outcomes

Clinical Trials Network Milestone Events

- **February 6, 2002** – Approval from the DOD HSRB for the use of UAB IRB as regulatory oversight and approval body for the conduct of clinical trials within the Network

- The following trials were activated at the network sites

    - **UAB 0009** – A Phase I Clinical and Pharmacokinetic Evaluation of Oral CI-1033 Given as a Single Dose Daily in Patients with Advanced Nonhematologic Malignancies
      Activation Date – 10/18/01
      Accrual Number – 2
    - **UAB 0028** – A Multicenter, Open-Label, Phase III, Randomized, Active-Controlled Trial Evaluating the Efficacy, Safety, and Pharmacokinetics of rhuMAb VEGF (BEVACIZUMAB), in Combination with Capecitabine Chemotherapy, in Subjects with Previously Treated Metastatic Breast Cancer
      Activation Date – 02/02
      Accrual Number – 12
    - **UAB 0047** – A Multicenter Phase III Randomized Trial Comparing Docetaxel in Combination with Doxorubicin and Cyclophosphamide (TAC) Versus Doxorubicin and Cyclophosphamide Followed by Docetaxel (AC → T) as Adjuvant Treatment of Operable Breast Cancer HER2NEU Negative Patients with Positive Axillary Lymph Nodes (BCIRG 005)
      Activation Date – 8/28/01
      Accrual Number – 24

- **UAB 0106** – A Multicenter Phase Ill Randomized Trial Comparing Doxorubicin and Cyclophosphamide Followed by Docetaxel (AC→T) With Doxorubicin and Cyclophosphamide Followed by Docetaxel and Trastuzumab (AC→TH) and With Docetaxel, Platinum Salt and Trastuzumab (TCH) in the Adjuvant Treatment of Node Positive and High Risk Node Negative Patients with Operable Breast Cancer Containing the Her2Neu Alteration
  Activation Date – 02/02
  Accrual Number - 5
- **UAB 0152** – A Multicenter Phase 2 Study of CI-1040 in Patients with Advanced Non-Small Cell Lung Cancer, Breast Cancer, Colon Cancer, or Pancreatic Cancer
  Activation Date – 02/02
  Accrual Number – 4

Conclusions

The UAB-CTN provides a unique setup for the conduct of early phase I/II as well as phase II/III breast cancer clinical trials in the community setting. The funding of clinical research centers within the community provides the impetus for committed and motivated community-based clinicians to conduct clinical trials in the community setting in exchange for access to such trials via a linkage to an academic center. Over the past 12 months we have been able to demonstrate that community based research centers have the patient base to support the conduct of clinical trials. Given the right setting, commitment to clinical research by the community based center, and committed and appropriately trained research staff, such community based research centers are capable of conducting high quality clinical research, and contributing to the achievements of the objectives of the clinical trials in a much shorter time span. This provides benefits for the participating centers, the study sponsors and most importantly the patients. We have also learned that clinical research at the community level has to be held at the same standard as at the academic centers. Given the dedication on part of the community practice and a cadre of well-trained research staff, the conduct of clinical trials within the community can succeed and be beneficial for all involved parties.

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Appendices

None.